

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in June 2002.

New Approvals

NADA Number: 141-200

Trade Name: EAZI-Breed™ CIDR® Cattle Insert
Ingredients: Progesterone
Sponsor: DEC International, Inc.
Approval Date: May 2, 2002
Status: Over-the-counter
Route: Intravaginal
Species: Beef cows, beef heifers, and dairy heifers
Drug Form: Insert
Concentration: 1.38 grams
Indications: For concurrent use with dinoprost tromethamine (Lutalyse® Sterile Solution):
1) Synchronization of estrus in suckled beef cows, and replacement beef and dairy heifers,
2) Advancement of first postpartum estrus in suckled beef cows and
3) Advancement of first pubertal estrus in replacement beef heifers.
Tolerance: 21CFR 556.540 Progesterone: Tolerances for residues of progesterone in uncooked edible tissues of heifers, steers and calves are the following: 3 parts per billion for muscle, 12 parts per billion for fat, 9 parts per billion for kidney, and 6 parts per billion for liver.
Withdrawal: 21 days
Exclusivity: 3 years

21CFR 529.1940, 522.690, and 510.600

Supplemental Approvals

NADA Number: 048-761

This supplemental application provides for the administration as a top dressing on feed in the form of a Type C medicated feed.

Trade Name: Aureomycin® 50, 90, or 100 Granular
Ingredients: Chlortetracycline
Sponsor: Alpharma, Inc.
Approval Date: January 24, 2002
Status: Over-the-counter
Route: Oral, via feed
Species: Calves, beef and non-lactating dairy cattle
Drug Form: Type A Medicated Article to make Type C medicated feeds.
Concentration: Chlortetracycline 50, 90, or 100 grams activity per pound of Type A Medicated Article.
Indications: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.
Tolerance: 21CFR 556.150 Chlortetracycline: Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, non-lactating dairy cows and calves of 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal: Zero days
Exclusivity: 3 years

21CFR 558.128

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Addition of Sponsor

Name: DEC International, Inc.
1919 South Stoughton Rd.
P.O. Box 8050
Madison, WI 53708-8050
Drug Labeler Code: 067080

Change of Sponsor Name

From: Akey, Inc.
P.O. Box 607
Lewisburg, OH 45338
To: North American Nutrition Companies, Inc.
C.S. 5002
6531 St., Rt. 503
Lewisburg, OH 45338
Drug labeler code: 017790

From: MoorMan's, Inc.
1000 North 30th St.
Quincy, IL 62305-3115
To: ADM Alliance Nutrition, Inc.
1000 North 30th St.
Quincy, IL 62305-3115
Drug labeler code: 021930

Change of Sponsor

NADA Numbers: 101-497, 101-498, 200-028

From: Lambert-Kay, A Division of Carter-Wallace, Inc.
To: Church & Dwight Co., Inc.
469 North Harrison St.
Princeton, NJ 08543-5297
Drug Labeler Code: 010237